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INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Article 36 and Rule 70)

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Applicant's or agent's file reference P641PC00	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/DK 03/00891	International filing date (day/month/year) 18.12.2003	Priority date (day/month/year) 08.01.2003
International Patent Classification (IPC) or both national classification and IPC A61N1/00		
Applicant MIBITECH APS et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

 These annexes consist of a total of 5 sheets.

3. This report contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand 21.07.2004	Date of completion of this report 11.01.2005
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer: Stern, M Telephone No. +49 89 2399-2239 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/DK 03/00891**

I. Basis of the report

1. With regard to the elements of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17):*

Description, Pages

1-19 as originally filed

Claims, Numbers

1-41 received on 10.11.2004 with letter of 08.11.2004

Drawings, Sheets

1/5-5/5 as originally filed

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY
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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-41
	No: Claims	
Inventive step (IS)	Yes: Claims	1-41
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-41
	No: Claims	

2. Citations and explanations

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/DK 03/00891

1. Of the documents cited in the international search report, the following will be addressed in the present communication (the numbering will be adhered to in the rest of the procedure):

D1: US-A-5 593 432

D2: GB-A-997 670

2. For the following reasons, the application fulfills the requirement of novelty and inventive step of Article 33 PCT.

Document D1, which is considered as representing the closest prior art, discloses a device comprising two electrodes (cf in D1, column 3, lines 6-12), a voltage supplying means, the output of which automatically changes in time between two different frequencies (cf in D1, claim 1; column 5, lines 18-20 and 27-31). Implicitly, the device has also means for shifting between an active mode in which an alternating output voltage signal is supplied across the two electrodes, and an off-mode, or standby mode, in which no alternating output voltage signal is supplied across the two electrodes.

Not disclosed in D1 is the feature after the last comma of claim 1, ie, that the shifting between these two modes is controlled as a function of current flowing between the two electrodes.

As explained in the first paragraph of page 10 of the application, this differentiating feature allows, eg, to determine the resistivity of the skin of selected skin points, which provides an indication of the proximity to an acupuncture point on the skin. Although such a search of acupuncture points in terms of the resistance, or the current, is already disclosed in document D2, this document fails to also disclose the control of such a current measurement for shifting between the two aforementioned modes. Also the other documents cited in the search report fail to disclose this.

Hence, the device recited in claim 1 satisfies the requirements of novelty and inventive step. Since dependent claims 2-41 define preferred embodiments of this device, they also satisfy the mentioned requirements.

CLAIMS filed on 8 November 2004 in response to the first written opinion

1. An electro-therapeutic device comprising:
 first and second electrodes or probes for making electrical contact to the body
 of an individual,
 voltage supplying means for supplying an alternating output voltage across
 said electrodes to pass an alternating current through the body of the individual, said
 voltage supply means being adapted for controlling the frequency of the output volt-
 age so that the output voltage frequency is automatically changing in time between
 a low frequency and a high frequency, said high frequency being higher than said
 low frequency, and
 means for shifting between a standby mode and an active mode, wherein
 when in standby mode no alternating output voltage signal is supplied across the
 first and second electrodes and when in active mode, the alternating output voltage
 signal is supplied across the first and second electrodes, said means for shifting
 between the standby mode and the active mode being adapted to control said shift-
 ing as a function of current flowing between the first electrode and the second elec-
 trode.
2. A device according to claim 1, wherein the mode shifting means is adapted to
 hold the device in the standby mode when no current is flowing between the first
 and second electrodes.
3. A device according to claim 1 or 2, wherein the mode shifting means is adapted to
 hold the device in the active mode when a current larger than or equal to a trigger
 current is flowing between the first and second electrodes.
4. A device according to claim 3, wherein the mode shifting means comprises a
 power converter and resistor means, and said trigger current generates a voltage
 drop across said resistor means whereby the power converter shifts from a standby
 mode to an active mode.
5. A device according to any of the preceding claims, wherein the voltage supply
 means is adapted for controlling the frequency of the output voltage so that the out-

put voltage frequency is changing between a low frequency and a high frequency at regular time intervals.

5 6. A device according to any of the preceding claims, wherein the voltage supply means is adapted for controlling the frequency of the output voltage so that the output voltage is changing in time between one or more time periods having a low frequency and one or more time periods having a high frequency.

10 7. A device according to any of the claims 1-6, wherein the low output voltage frequency is in the range of 0.5-10 Hz.

8. A device according to claim 7, wherein the low output voltage frequency is in the range of 1-5 Hz.

15 9. A device according to claim 8, wherein the low output voltage frequency is about 2 Hz.

10. A device according to any of the claims 1-9, wherein the high output voltage frequency is in the range of 12-50 Hz.

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11. A device according to claim 10, wherein the high output voltage frequency is in the range of 15-40 Hz.

25 12. A device according to claim 11, wherein the high output voltage frequency is about 15 Hz.

13. A device according to any of the claims 1-9, wherein the high output voltage frequency is in the range of 40-300 Hz.

30 14. A device according to claim 13, wherein the high output voltage frequency is in the range of 60-200 Hz.

15. A device according to claim 14, wherein the high output voltage frequency is in the range of 75-150 Hz.

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16. A device according to claim 15, wherein the high output voltage frequency is about 100 Hz.

5 17. A device according to any of the claims 1-16, wherein the voltage supply means is adapted for controlling the frequency of the output voltage so that the frequency of the output voltage is changed in cycles, each cycle comprising a first time period of low frequency and a second time period of high frequency.

10 18. A device according to claim 17, wherein a cycle time defined by the total time of the first time period and the second time period is in the range of 3-15 seconds.

19. A device according to claim 17, wherein a cycle time defined by the total time of the first time period and the second time period is in the range of 4-10 seconds.

15 20. A device according to claim 17, wherein a cycle time defined by the total time of the first time period and the second time period is in the range of 5-6 seconds.

21. A device according to claim 17, wherein a cycle time defined by the total time of the first time period and the second time period is about 6 seconds.

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22. A device according to any of the claims 1-21, wherein a time period of low frequency is in the range of 1-6 seconds.

25 23. A device according to any of the claims 1-21, wherein a time period of low frequency is in the range of 2-4 seconds.

24. A device according to any of the claims 1-21, wherein a time period of low frequency is about 3 seconds.

30 25. A device according to any of the claims 1-24, wherein a time period of high frequency is in the range of 1-6 seconds.

26. A device according to any of the claims 1-24, wherein a time period of high frequency is in the range of 2-4 seconds.

35

27. A device according to any of the claims 1-24, wherein a time period of high frequency is about 3 seconds.

28. A device according to any of the claims 1-27, said device further comprising timing means for controlling the alternating output voltage to be applied for a predetermined time period.

29. A device according to any of the claims 1-28, wherein the first electrode is an active electrode for making electrical contact to a selected point of the body of a patient, and the second electrode is a passive electrode for making electrical contact over a relatively large area of the body of the individual when compared to the selected point area.

30. A device according to any of the claims 1-29, said device comprising a casing which is holdable in the hand of an individual, said first electrode being mounted to the casing and said second electrode being disposed on the casing for making electrical contact with the hand of the individual.

31. A device according to claim 30, wherein the casing is elongate and the first electrode is mounted at one end of the casing, being electrically isolated from the body of the casing.

32. A device according to claim 31, wherein at least part of the body of said casing is made of an electrically conducting material and the second electrode is in electrical contact with said electrically conducting part of the body of the casing.

33. A device according to any of the claims 1-32, said device further comprising resistance detecting means for detecting when the first electrode is located at or near a low resistance point on the body of the individual, said resistance detecting means having means for detecting variations in the resistance between the first and second electrodes.

34. A device according to claim 33, said device further comprising means for providing an audible signal representative of the resistance.

35. A device according to claim 34, wherein the means for providing an audible signal is adapted to emit a sound which changes in volume or pitch, the volume or pitch being proportional to or a function of the resistance.

5 36. A device according to any of the claims 33-35, said device further comprising means for providing a visible signal representative of the resistance.

37. A device according to any of the preceding claims, wherein the voltage supplying means is adapted to supply an alternating output voltage having a voltage swing
10 in the range of 2-10 V, in the range of 3-8 V, in the range of 4-6 V, or about 5 V.

38. A device according to any of the claims 1-36, wherein the voltage supplying means is adapted to supply an alternating output voltage having a voltage swing in the range of 10-50 V, in the range of 12-40 V, in the range of 15-35 V, or about 20 V
15 or about 25 V.

39. A device according to any of the preceding claims, wherein the voltage supplying means is adapted to pass an alternating current through the body of said individual in the range of 0.01-3 mA, or in the range of 0.02-1 mA.
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40. A device according to any of the preceding claims, wherein the first and/or second electrodes have a conductive surface comprising a non-oxidising metal.

41. A device according to claim 40, wherein the non-oxidising metal is selected from
25 a group of materials comprising gold, silver and a platinum/chrome coating.